

Application No. 10/601,212
Reply to Office Action of February 23, 2007

Amendments to the Drawings

New Replacement Sheet 2/9 is presented and enclosed as an Attachment. New Replacement Sheet 2/9 has been amended to conform Fig. 2A to the Specification. Specifically Fig. 2A includes reference numeral 335 in duplicate. Reference numeral 335 (closest to reference numeral 305) has been amended to reference numeral 315 as set forth in page 8 line 12 of the Specification.

ATTACHMENT:

One Replacement Sheet.

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REMARKS

In view of the above amendments and arguments submitted herewith, Applicant respectfully submits that the pending application is in condition for allowance.

I. Status of the Claims

Claims 1-12 are cancelled.

Claims 33-38 have been added. Support for these new claims can be found, *inter alia*, in the original listing of claims and throughout the Specification. The present application is a continuation of PCT Application Serial No. PCT/US01/50102 filed December 21, 2001, which is a continuation of U.S. Application Serial No. 09/745,905 filed on December 21, 2000, which issued on May 14, 2002 as U.S. Patent No. 6,387,078 ('the '078 patent').

Independent claim 33 is identical to independent claim 13 of the '078 patent except that "a splitter attached to the *plunger shaft* ..." has been changed to "a splitter attached to the *housing*...." Claims 34-38 are identical to claims 14-18 of the '078 patent except for their dependency to claim 33 of the present application.

Claims 33-38 are being added to the present application because of an error identified in claim 13 of the '078 patent. This was an inadvertant error which occurred in good faith. As recited in claim 13 of the '078 patent, the automatic injecting apparatus comprises, *inter alia*, "a splitter attached to the *plunger shaft* distally to the spring-to-plunger coupling...." An automatic injecting apparatus as recited in claim 13 of the '078 patent would be inoperable as a splitter 125 attached or fixed to the plunger shaft 300 would never engage the spring-to-plunger coupling 300. *See Fig. 1 of the '078 patent.* As shown in Fig. 2B of the '078 patent, the splitter 125 is attached to the housing 115 and not the plunger shaft 300.

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Moreover, Applicant respectfully submits that the changes from claim 13 of the '078 to that of claim 33 of the present application do not constitute new matter nor would such changes require any additional search by the Examiner.

No new matter has been introduced by any new claim.

Claims 13-38 are currently pending.

II. Rejections Under 35 U.S.C. §102

Claims 13-32 have been rejected under 35 U.S.C. §102, as being anticipated by U.S. Patent No. 5,626,566 to Petersen *et al.* ("Petersen"). Regarding claims 13-16, the Examiner contends that "Petersen discloses applicant's invention substantially as claimed." Office Action page 2, paragraph 4. Applicant respectfully traverses this rejection.

In particular, regarding claims 13-16, the Examiner contends that Petersen discloses a plunger 23 which cooperates with a first chamber 31. The Examiner further contends that the plunger 23 has a first engaging member 21 defined thereon. *See* Office Action page 2, paragraph 5.

Moreover, the Examiner contends that Petersen discloses "a damper pad disposed between said housing and said first chamber so than an impact of said first chamber with said housing is damped." Office Action page 3, paragraph 5. As such, Applicant has construed the Examiner's rejection as stated in paragraph 5 to apply to claim 17 as well as claims 13-16 and respectfully requests that the Examiner confirm in the next office action whether the rejection on page 2, paragraph 5 of the February 23, 2007 Office Action should be correctly applied to claims 13-17.

Petersen discloses a large dose syringe pen that allows for repetitive injections of a medicine in which the dose can be individually set. As shown in Fig. 2, the syringe pen includes a plunger (or piston rod) 23 configured with external threads and a dosing member 18. The

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dosing member 18 is coupled to the plunger 23 by a piston drive. The piston drive includes a coupling part 21 and a drive nut 22 having internal threads for engaging the external threads of the plunger 23. Col. 4, lines 38-47. To invoke an injection, a patient depresses the button 30 which causes the spindle 10 to rotate and thereby cause rotation of the piston drive to invoke or drive the plunger 23 distally.

Claim 13 recites, *inter alia*, “[a]n injection apparatus comprising: ... a plunger ... having a first engaging member defined thereon....” As shown in Fig. 2A of the Specification, (*see attached Replacement Sheet 2/9*) the plunger 300 has a first engaging member 315 defined thereon configured as a circumferential groove *i.e.*, a detent in the embodiment shown. The first engaging member 315 is configured for engagement with the second engaging member 365 (configured as a radial lip) of the spring-to-plunger coupling 340 as best shown in the embodiment of Fig. 7. Engagement of the first 315 and second 365 engaging members secures the coupling 340 to the plunger 300 until the second engaging member 365 of the coupling 340 is disengaged from the first engaging member 315 of the plunger 300.

Applicant respectfully submits that contrary to the Examiner’s contention Petersen does not disclose a plunger having a first engaging member. The coupling part 21, as described above, is separate and distinct from the plunger 23. *See also* Petersen Fig. 7. The coupling part 21, in conjunction with the drive nut 22, form a piston drive that is merely coupled to the plunger 23 and not part of the plunger 23 or defined thereon.

The Examiner also contends that Petersen discloses “a coupling having a second engaging member defined in an inner periphery [threads col 4, line 42], said first and second engaging members being releasably engaged to one another....” Office Action, page 2, paragraph 5. The second engaging member discussed by the Examiner being the internal threads of the drive nut 22. Col. 4, line 42.

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Claim 13 recites, *inter alia*, “a coupling having a second engaging member defined in an inner periphery, said first and second engaging members being releasably engaged to one another....”

Contrary to the Examiner’s contention, Petersen is completely silent as to any teaching of the internal threads of the drive nut 22 being releasably engageable with the coupling part 21. As shown in Fig. 2, the coupling part 21 and the internal threads of the drive nut 22 are not configured for engaging one another. Instead, the internal threads of the drive nut 22 are configured for “engaging an external thread on a piston rod 23....” Col. 4, line 42. Moreover, even if the external threads of the piston rod 23 were to be construed as a first engaging member, Petersen is totally silent as to any teaching of the piston rod 23 and the drive nut 22 being releasably engageable.

The Examiner further contends that Petersen discloses “a first spring 25 acting on said coupling to urge said plunger in a first direction until said coupling contacts a surface [col 4 line 50-65, reaches ‘edge’], wherein said surface causes said second engaging member to move away from said plunger so that said first and second engaging members are released from one another [col 5 lines 40-50]....” Office Action, pages 2-3, paragraph 5.

Claim 13 recites, *inter alia*, “a first spring acting on said coupling to urge said plunger in a first direction until said coupling contacts a surface, wherein said surface causes said second engaging member to move away from said plunger so that said first and second engaging members are released from one another.”

Contrary to the Examiner’s contention, the first spring 25, does not act on the drive nut 22 (*i.e.*, the coupling as asserted by the Examiner) to urge the plunger or piston rod 23 in a first direction. As shown in Fig. 2, the first spring 25 acts on the flange 27 of the bushing 28 on one end and the shoulder 26 of the tubular member 8 on the other end. *See also* col. 4, lines 53-58. The spring 25 merely serves to urge coupling parts 20 and 21 together. *See* col. 4, lines 48-58.

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Moreover, instead of the spring 25, it is the internal threads of the drive nut 22 and the rotation thereof that effectuates movement of the plunger or piston rod 23 in a first direction. As such, Petersen is completely silent as to any teaching or disclosure regarding a first spring acting on a coupling to urge a plunger in a first direction until said coupling contacts a surface.

In sum, Applicant respectfully submits that Petersen does not disclose each and every element of independent claim 13. As such, Applicant respectfully submits that Petersen does not anticipate independent claim 13. Therefore, withdrawal of this rejection is respectfully requested. In addition, Applicant respectfully submits that claims 14-17 should be allowed based at least upon their dependency, directly or indirectly, to independent claim 13.

Regarding claims 18-26, the Examiner contends that Petersen discloses, *inter alia*, an injection apparatus comprising “a housing being disposed about said syringe assembly so that said syringe assembly is movable in said housing between a retracted position and an extended position....” Office Action page 3, paragraph 6. Regarding claims 27-32, the Examiner contends that Petersen discloses, *inter alia*, an injection apparatus comprising a “syringe assembly being movably disposed in said housing so that said housing conceals said needle in a first position and said needle extends from said housing in a second position....” Office Action page 5, paragraph 7.

Petersen discloses a large dose pen as shown in Fig. 1. The large dose pen includes a cartridge holder 2 configured to hold a cartridge or ampoule 31 in a fixed position. As shown in Fig. 1, the cartridge 31 and needle hub assembly is held in a fixed position such that no axial movement of the cartridge 31/needle hub assembly is possible. *See* col. 3, lines 52-59. This is accomplished by “protrusions protruding inwardly from the cartridge holder wall to hold back the cartridge in the holder and cooperat[es] with an adapter top 5 on the neck part of the cartridge.” Col. 3, lines 53-56. The “adaptor top 5 protrudes from the end of the cartridge holder 2 and is provided with an outer thread onto which a needle hub 6 is screwed to secure the cartridge in the holder 2.” Col. 3, lines 56-59. Moreover, the cartridge holder 2 secures the cartridge 31/needle

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hub assembly in the housing such that the needle is extending from the housing with a protective cap 3 being merely “passed over the cartridge holder 2 when the syringe is not in use...” col. 3, lines 59-61, for protecting the user from the permanently extending needle.

As such, Applicant respectfully submits that Petersen does not disclose “a housing being disposed about said syringe assembly so that said syringe assembly is movable in said housing between a retracted position and an extended position” as claimed in independent claim 18 or a “syringe assembly being movably disposed in said housing so that said housing conceals said needle in a first position and said needle extends from said housing in a second position” as claimed in independent claim 27. Accordingly, Applicant respectfully submits that Petersen does not anticipate independent claim 18 or 27. Therefore, withdrawal of this rejection is respectfully requested. In addition, Applicant respectfully submits that claims 19-26 and 27-32 should be allowed based at least upon their dependency, directly or indirectly, to independent claim 18 or 27 respectively.

Claims 33-38 have been added and Applicant respectfully requests allowance of these claims for the reasons discussed above in Section I under Status of the Claims.

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CONCLUSION

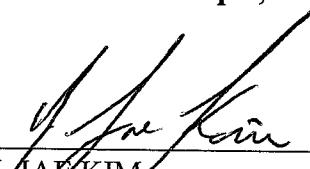
In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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(Date)

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